Accession Number:	A38778	**ECRI Priority:**	High	**Published:**	02/22/2022
Channel:	Devices	**FDA:**	Class I	**Last Updated:**	05/06/2022

Abbott—Similac, Alimentum, and EleCare Powder Formulas: Lots Manufactured at Sturgis, MI, Plant May Be Contaminated with Cronobacter sakazakii and/or Salmonella Newport

Product Identifier(s)

The recall is isolated to the below powder infant formulas manufactured at the Sturgis, MI, plant, with multidigit lot number on the bottom of the container starting with the first two digits 22 through 37, containing K8, SH, or Z2, and with an expiration date of 2022 Apr 1 or later.

Product	Abbott Nutrition Div Abbott Laboratories Inc Model
Powder Infant Formula	Alimentum, EleCare, Similac

Manufacturer(s)

Abbott Nutrition Div Abbott Laboratories Inc, 2900 Easton Square Pl, Columbus, OH 43219, United States

Problem

In a February 17, 2022, Press Release, Abbott initiated a recall of the above powder infant formula after four consumer complaints related to *Cronobacter sakazakii* or *Salmonella* Newport in infants who had consumed powder infant formula manufactured in the Sturgis, MI, facility. Abbott also states that as part of its quality process, it conducts routine testing for *Cronobacter sakazakii* and other pathogens in its manufacturing facilities; during testing in its Sturgis, MI, facility, the firm found evidence of *Cronobacter sakazakii* in the plant in non-product contact areas. Abbott further states that it found no evidence of *Salmonella* Newport; this investigation is ongoing. Abbott states that no distributed product has tested positive for the presence of either bacteria, and the firm continues to test. Abbott also states that it is recalling the powder formula manufactured in this facility with an expiration date of 2022 Apr 1. Products under recall have a multidigit number on the bottom of the container starting with the first two digits 22 through 37, and containing K8, SH, or Z2, with an expiration date of 2022 Apr 1. In a February 17, 2022, News Release, FDA warned consumers against use of affected powder infant formula.

Action Needed

Identify, isolate, and discontinue use of any affected powder infant formula in your inventory. To determine whether the product you have is included in this recall, visit similacrecall.com and type in the code on the bottom of the package, or call (800) 986-8540 (U.S.) and follow the instructions provided. FDA is advising consumers not to use Similac, Alimentum, or EleCare powdered infant formulas if:

- The first two digits of the code are 22 through 37; and
- The code on the container contains K8, SH, or Z2; and
- The expiration date is 4-1-2022 (APR 2022) or later.

Abbott states that no action is needed for previously consumed product. Abbott states that this recall does not include any metabolic deficiency nutrition formulas, and that no Abbott liquid formulas, other powder formula brands, or nutrition products manufactured at other facilities are affected by this recall. FDA states that parents and caregivers of infants who have used these products and are concerned about the health of their child should contact their child's healthcare provider. If your child is experiencing any symptoms outlined in the News Release, notify your child's healthcare provider and seek medical care for your child immediately. FDA also states that parents and caregivers should never dilute infant formula, and should not make or feed homemade infant formula to infants. FDA further states that if your regular formula is not available, contact your child's healthcare provider for recommendations on changing feeding practices. FDA states that it is continuing to investigate, and will provide additional consumer safety information when it becomes available. For more details, see the Abbott Press Release as well as FDA's News Release and Investigation listing.

For Further Information:
Abbott
Website: Click here

Geographic Region(s)

(Impact in additional regions has not been identified or ruled out at the time of this posting), U.S.

Suggested Distribution

Nursery, Nursing, Obstetrics/Gynecology/Labor and Delivery, NICU, Pharmacy, Materials Management

Comment

- ECRI previously covered this action in the Food and Pharmaceuticals channels as Alert F11052.
- This alert is a living document and may be updated when ECRI receives additional information.

Miscellaneous

References:
Abbott. Press releases. Abbott voluntarily recalls powder formulas manufactured at one plant [online]. 2022 Feb 17 [cited 2022 Feb 18]. Available from Internet: Click here.
United States:

- Food and Drug Administration. News release—FDA warns consumers not to use certain powdered infant formula produced in Abbott Nutrition's facility in Sturgis, Michigan [online]. 2022 Feb 17 [cited 2022 Feb 22]. Available from Internet: Click here.
- Food and Drug Administration. FDA investigation of Cronobacter and Salmonella complaints: powdered infant formula (February 2022) [online]. 2022 Feb 20 [cited 2022 Feb 22]. Available from Internet: Click here.

Accession Number:	A38778 01	**ECRI Priority:**	High	**Published:**	02/23/2022
Channel:	Devices, Pharmaceutical, Food	**FDA:**	Not Specified	**Last Updated:**	03/03/2022

Abbott—Similac, Alimentum, and EleCare Powder Formulas: Lots Manufactured at Sturgis, MI, Plant May Be Contaminated with Cronobacter sakazakii and/or Salmonella Newport [Update]

Product Identifier(s)

The recall is isolated to the below powder infant formulas manufactured at the Sturgis, MI, plant, with multidigit lot number on the bottom of the container starting with the first two digits 22 through 37, containing K8, SH, or Z2, and with an expiration date of 2022 Apr 1 or later.

Product	Abbott Nutrition Div Abbott Laboratories Inc Item No.
ALIM 12.1OZ PWD 6CT	64715
ALIM 19.8OZ PWD 4CT	64719
ALIM ADV 7OZ PWD 6CT GR	64717
SIM ALIM TODD HMO 12.1OZ PWD 6CT	68398
ELECARE IN 14.1OZ PWD 6CT	55251
ELECARE IN 14.1OZ PWD 6CT PRI	5525135
ELECARE JR BAN 14.1OZ PWD 6CT	66275
ELECARE JR CHO 14.1OZ PWD 6CT	66273
ELECARE JR UNFL 14.1OZ PWD 6CT	55253
ELECARE JR VAN 14.1OZ PWD 6CT	56585
HMF 0.9G PWD 3-50PKS	54598
SIM 3TC 34OZ PWD 6CT	68610
SIM 3TC ADV 20.6OZ PWD 4CT	68063
SIM 3TC ADV 30.3OZ PWD 4CT	68065
SIM 3TC ADV 30.3OZ PWD 4CT ECOM	68195
SIM 3TC ADV 40OZ PWD 6CT CLUB	68067
SIM 3TC ADV 7OZ PWD 6CT GR	68109
SIM 3TC SENS 20.1OZ PWD 4CT	68070
SIM 3TC SENS 29.5OZ PWD 4CT	68072
SIM 3TC SENS 29.5OZ PWD 4CT ECOM	68196
SIM 3TC SENS 34OZ PWD 6CT	68611
SIM 3TC SENS 40OZ PWD 6CT CLUB	68074

SIM 3TC SENS 7OZ PWD 6CT GR	68118
SIM ADV 12.4OZ PWD 6CT	5595776
SIM ADV 20.6OZ PWD 6CT	68084
SIM ADV 34OZ PWD 2CT	67549
SIM ORG 20.6OZ PWD 4CT	68092
SIM ORG A2 20.6OZ PWD 4CT	68099
SIM ORG A2 TOD 20.6OZ PWD 4CT	68104
SIM PRO-ADV 2.13LB/34OZ PWD 6CT CLUB	66655
SIM PRO-ADV 20.6OZ PWD 4CT	68088
SIM PRO-ADV 2FL HMO 7OZ PWD 6CT GR	67922
SIM PRO-SENS 1.41LB/22.5OZ PWD 4CT	66084
SIM PRO-SENS 2.13LB/34OZ PWD 6CT CLUB	66657
SIM PRO-SENS 20.1OZ PWD 4CT	68090
SIM PRO-SENS 2FL HMO 7OZ PWD 6CT GR	67923
SIM PRO-TC 20.1OZ PWD 4CT	68107
SIM PRO-TC 2FL HMO 7OZ PWD 6CT GR	67925
SIM PRO-TTL CMFRT 34OZ PWD 6CT CLUB	66798
SIM SENS 12.0OZ PWD 6CT	5753978
SIM SENS 20.1OZ PWD 6CT	68082
SIM SENS 34OZ PWD 2CT	67550
SIM SENS SPIT UP ES 12.0OZ PWD 6CT	5095976
SIM SPIT UP 20.1OZ PWD 6CT	68086
SIM SPIT UP NGMO 7OZ PWD 6CT GR	67927
SIM TOTAL COMFORT 12OZ PWD 6CT	62599

Manufacturer(s)

Abbott Nutrition Div Abbott Laboratories Inc, 2900 Easton Square Pl, Columbus, OH 43219, United States

Summary

Update Reason: Specific affected product added to Product Identifier field. This Alert provides new information based on a February 18, 2022, Urgent Voluntary Product Recall letter submitted by ECRI member hospitals regarding Alert A38778.

Problem

In a February 17, 2022, Press Release, Abbott initiated a recall of the above powder infant formula after four consumer complaints related to *Cronobacter sakazakii* or *Salmonella* Newport in infants who had consumed powder infant formula manufactured in the Sturgis, MI, facility. Abbott also states that as part of its quality process, it conducts routine testing for *Cronobacter sakazakii* and other pathogens in its manufacturing facilities; during testing in its Sturgis, MI, facility, the firm found evidence of *Cronobacter sakazakii* in the plant in non-product contact areas. Abbott further states that it found no evidence of *Salmonella* Newport; this investigation is ongoing. Abbott states that no distributed product has tested positive for the presence of either bacteria, and the firm continues to test. Abbott also states that it is recalling the powder formula manufactured in this facility with an expiration date of 2022 Apr 1. Products under recall have a multidigit number on the bottom of the container starting with the first two digits 22 through 37, and containing K8, SH, or Z2, with an expiration date of 2022 Apr 1. In a February 17, 2022, News Release, FDA warned consumers against use of affected powder infant formula.

Action Needed

The following actions are those listed in Alert A38778. Identify, isolate, and discontinue use of any affected powder infant formula in your inventory. To determine whether the product you have is included in this recall, click here and type in the code on the bottom of the package, or call (800) 986-8540 (U.S.) and follow the instructions provided. FDA is advising consumers not to use Similac, Alimentum, or EleCare powdered infant formulas if:

- The first two digits of the code are 22 through 37; and
- The code on the container contains K8, SH, or Z2; and
- The expiration date is 4-1-2022 (APR 2022) or later.

Abbott states that no action is needed for previously consumed product. Abbott states that this recall does not include any metabolic deficiency nutrition formulas, and that no Abbott liquid formulas, other powder formula brands, or nutrition products manufactured at other facilities are affected by this recall. FDA states that parents and caregivers of infants who have used these products and are concerned about the health of their child should contact their child's healthcare provider. If your child is experiencing any symptoms outlined in the News Release, notify your child's healthcare provider and seek medical care for your child immediately. FDA also states that parents and caregivers should never dilute infant formula, and should not make or feed homemade infant formula to infants. FDA further states that if your regular formula is not available, contact your child's healthcare provider for recommendations on changing feeding practices. FDA states that it is continuing to investigate, and will provide additional consumer safety information when it becomes available. For more details, see the Abbott Press Release as well as FDA's News Release and Investigation listing.

For Further Information:
Abbott consumer relations representative
Tel.: (800) 986-8540
Website: Click here

Geographic Region(s)

(Impact in additional regions has not been identified or ruled out at the time of this posting), U.S.

Suggested Distribution

Infection Control, Nursery, Nursing, Obstetrics/Gynecology/Labor and Delivery, NICU, Pharmacy, Materials Management

Comment

- ECRI previously covered this action in the Food and Pharmaceuticals channels as Alert F11052.

- This alert is a living document and may be updated when ECRI receives additional information.

Miscellaneous

References:
Abbott. Press releases. Abbott voluntarily recalls powder formulas manufactured at one plant [online]. 2022 Feb 17 [cited 2022 Feb 18]. Available from Internet: Click here.
United States:

- Food and Drug Administration. News release—FDA warns consumers not to use certain powdered infant formula produced in Abbott Nutrition's facility in Sturgis, Michigan [online]. 2022 Feb 17 [cited 2022 Feb 22]. Available from Internet: Click here.
- Food and Drug Administration. FDA investigation of Cronobacter and Salmonella complaints: powdered infant formula (February 2022) [online]. 2022 Feb 20 [cited 2022 Feb 22]. Available from Internet: Click here.

Accession Number:	A38778 02	**ECRI Priority:**	High	**Published:**	03/01/2022
Channel:	Devices, Pharmaceutical, Food	**FDA:**	Not Specified	**Last Updated:**	03/01/2022

Abbott—Similac PM 60/40 Infant Powder Formula: Lots Manufactured at Sturgis, MI, Plant May Be Contaminated with Cronobacter sakazakii [Update]

Product Identifier(s)

Only product manufactured the Sturgis, MI, plant is affected. Lot number 27032K80 is for individual cans. Lot number 27032K800 is for cases.

Product	Abbott Nutrition Div Abbott Laboratories Inc Model	Lot No.
Infant Powder Formula	Similac PM 60/40	27032K80, 27032K800

Manufacturer(s)

Abbott Nutrition Div Abbott Laboratories Inc, 2900 Easton Square Pl, Columbus, OH 43219, United States

Summary

Update Reason: Additional recalled product provided in Product Identifier field; new Problem and Action Needed information. This Alert provides new information based on a February 28, 2022, Urgent Voluntary Product Recall letter submitted by ECRI member hospitals regarding Alerts A38778 and A38778 01.

Problem

In a February 28, 2022, Urgent Voluntary Product Recall letter submitted by ECRI member hospitals, Abbott states that it is recalling the above lot of infant powder formula manufactured in Sturgis, MI. This is in addition to the lots of Similac, Alimentum, and EleCare powder formula that were recalled on February 17, 2022 (see Alerts A38778 and A38778 01). Abbott also states that this action comes after the firm learned of the death of an infant who tested who positive for *Cronobacter sakazakii* and who the firm was informed had consumed Similac PM 60/40 from the above lot. Abbott further states that this case is under investigation, and at this time the cause of the infant's *Cronobacter sakazakii* infection has not been determined. Abbott states that as part of its quality process, it conducts routine testing for *Cronobacter sakazakii* and other pathogens in its manufacturing facilities; during testing in its Sturgis, MI, facility, the firm found evidence of *Cronobacter sakazakii* in the plant in non-product contact areas. Abbott also states that no distributed product has tested positive for the presence of *Cronobacter sakazakii*. Abbott further states that recently tested retained product samples of the above lot were negative for *Cronobacter.* Abbott states that all infant formula powder finished products are tested for *Cronobacter* and other pathogens, and they must test negative before any product is released. The manufacturer has not confirmed the information provided in the source material.

Action Needed

Identify and isolate any affected powder infant formula in your inventory. If you have affected product, verify that you have received the February 28, 2022, Urgent Voluntary Product Recall letter from Abbott. Do not distribute or dispose of recalled product, and use the following instructions to arrange for product return:

- To schedule recalled product pick up, contact ABF by telephone at (866) 643-9477 or by e-mail at abbott@arcb.com. The carrier will provide a returns authorization (RA) number and a Bill of Lading.
- Put a placard on every box/pallet referencing the RA number.
- Upon receipt of returned product, Abbott records the product and will issue credit to customers based on product returned.
- For questions on returns and other general information, contact the Abbott customer service department by telephone using the information below.

Parents and caregivers should do the following:

- Look for lot 27032K80 on the bottom of the Similac PM 60/40 can (see images in the letter).
- If you have this lot, do not consume it and do not dispose of the product.
- Click here and type in the lot on the bottom of the product into the lot locator, and follow the instructions on how to return the product.
- For questions on returns and other general information, contact the Abbott consumer relations department by telephone using the information below.

For Further Information:
Abbott customer service department
Tel.: (800) 551-5838, 8:30 a.m. to 5 p.m. Eastern time, Monday through Friday
Abbott consumer relations department
Tel.: (800) 986-8540, 8:30 a.m. to 5 p.m. Eastern time, Monday through Friday
Website: Click here

Geographic Region(s)

(Impact in additional regions has not been identified or ruled out at the time of this posting), U.S.

Suggested Distribution

Infection Control, Nursery, Nursing, Obstetrics/Gynecology/Labor and Delivery, NICU, Pharmacy, Materials Management

Comment

- This alert is a living document and may be updated when ECRI receives additional information.

Miscellaneous

References:
Abbott. Press releases. Abbott voluntarily recalls powder formulas manufactured at one plant [online]. 2022 Feb 17 [cited 2022 Feb 18]. Available from Internet: Click here.
United States:

- Food and Drug Administration. News release—FDA warns consumers not to use certain powdered infant formula produced in Abbott Nutrition's facility in Sturgis, Michigan [online]. 2022 Feb 17 [cited 2022 Feb 22]. Available from Internet: Click here.
- Food and Drug Administration. FDA investigation of Cronobacter and Salmonella complaints: powdered infant formula (February 2022) [online]. 2022 Feb 20 [cited 2022 Feb 22]. Available from Internet: Click here.

Accession Number:	A38778 03	**ECRI Priority:**	High	**Published:**	03/04/2022
Channel:	Devices, Pharmaceutical, Food	**FDA:**	Not Specified	**Last Updated:**	03/04/2022

McKesson—Abbott Similac, Alimentum, and EleCare Powder Formulas: Lots Manufactured at Sturgis, MI, Plant May Be Contaminated with Cronobacter sakazakii and/or Salmonella Newport

Product Identifier(s)

The recall is isolated to the below powder infant formulas manufactured at the Sturgis, MI, plant, with a multidigit lot number on the bottom of the container starting with the first two digits 22 through 37, containing K8, SH, or Z2, and with an expiration date of 2022 Apr 1 or later.

Product	Abbott Nutrition Div Abbott Laboratories Inc NDC	Lot No.
ELECARE JR UNFL PWD 14.1OZ	70074055254	23441Z200, 25715Z200, 26723Z200, 26724Z200, 26858Z200, 27923Z200, 27924Z200, 27932Z200, 27934Z200, 29265Z200, 30390Z200, 30407Z200, 31408Z200, 34013Z200, 34774Z200, 35024Z200, 35029Z200, 36153Z200
ELECARE JR BAN PWD 14.1OZ	70074066276	23415Z200, 25716Z200, 27935Z200, 29264Z200, 31409Z200, 34775Z200, 35028Z200
ELECARE JR CHOC PWD 14.1OZ	70074066271	36154Z200, 34935Z200, 28129Z200, 30400Z200, 24532Z200
ELECARE JR VAN PWD 14.1OZ	70074056586	24531Z200, 26722Z200, 26808Z200, 26859Z200, 28128Z200, 28139Z200, 28140Z200, 30391Z200, 34772Z200, 34934Z200, 36147Z200
ELECARE UNFL +DHA/ARA 14.1OZ	70074053511	22331Z200, 23377Z200, 23438Z200, 23439Z200, 25562Z200, 25562Z220, 25563Z200, 25729Z200, 25730Z200, 26731Z200, 27922Z200, 27931Z200, 28124Z200, 28125Z200, 28126Z200, 30291Z200, 30292Z200, 30517Z200, 30518Z200, 31392Z200, 31402Z200, 32421Z200, 32684Z200, 33694Z200, 33695Z200, 34012Z200, 34769Z200, 34770Z200, 34771Z200, 34771Z210, 35023Z200, 35032Z200, 36149Z200, 36150Z200, 36151Z200
ELECARE DHA/ARA INF PWD 14.1OZ	70074053511	22331Z200, 23377Z200, 23438Z200, 23439Z200, 25562Z200, 25562Z220, 25563Z200, 25729Z200, 25730Z200, 26731Z200, 27922Z200, 27931Z200, 28124Z200, 28125Z200, 28126Z200, 30291Z200, 30292Z200, 30517Z200, 30518Z200, 31392Z200, 31402Z200, 32421Z200, 32684Z200, 33694Z200, 33695Z200, 34012Z200, 34769Z200, 34770Z200, 34771Z200, 34771Z210, 35023Z200, 35032Z200, 36149Z200, 36150Z200, 36151Z200
SIMILAC ADV PWD	70074055958	23403K800, 23404K800, 23410K800, 23437K800, 24476K800, 24477K800, 24478K800, 24492K800, 24519K800, 25578K800, 25580K800, 25597K800, 25602K800, 25680K800, 25697K800, 26753K800, 26755K800, 26776K800, 26793K800, 26846K800, 26848K800, 26850K800, 26851K800, 27002K800, 27895K800, 27897K800, 27901K800, 27904K800, 27906K800, 27962K800, 27965K800, 27968K800, 27969K800, 28004K800, 28006K800, 28009K800, 28028K800, 28093K800, 28094K800, 28095K800,

		28109K800, 28110K800, 28112K800, 28113K800, 28115K800, 28116K800, 28150K800, 29196K800, 29197K800, 29223K800, 29227K800, 29251K800, 29252K800, 29253K800, 29254K800, 29257K800, 30324K800, 30347K800, 30348K800, 30350K800, 30371K800, 30373K800, 31477K800, 31485K800, 31505K800, 31506K800, 32596K800, 32637K800, 33786K800, 33791K800, 33833K800, 34793K800
SIMILAC ALIMEN PWD 12.1OZ CS6	70074064712	23380Z260, 24464Z261, 24528Z260, 24529Z260, 24533Z260, 24534Z260, 25661Z260, 25662Z260, 25663Z260, 25664Z260, 26726Z260, 26727Z260, 26728Z260, 26732Z260, 26733Z260, 26805Z260, 26806Z260, 26807Z260, 27925Z260, 27941Z260, 27942Z260, 27943Z260, 28042Z260, 28044Z260, 29260Z260, 29261Z260, 29262Z260, 29268Z260, 29269Z260, 29270Z260, 29271Z260, 30286Z260, 30287Z260, 30375Z260, 30376Z210, 30377Z200, 30379Z260, 30380Z260, 30381Z260, 30382Z260, 32404Z260, 32405Z260, 32417Z260, 32418Z220, 32425Z200, 33426Z200, 33427Z200, 33428Z200, 33696Z200, 33697Z200, 36155Z261
SIMILAC HUMN MLK INST50X.031Z	70074054599	26921Z200, 28162Z200, 28166Z200, 30513Z200, 30521Z200, 32660Z200, 35112Z200, 35113Z200
SIMILAC PROADV HMO 1.45LB CS4	70074066080	23407SH00, 23409SH00, 24480SH00, 24523SH00, 25598SH00, 25600SH00, 25695SH00, 25736SH00, 25780SH00, 26762SH00, 26764SH00, 26831SH00
SIMILAC PROSENS HMO 1.41LB CS4	70074066082	23421SH00, 24509SH00, 24510SH00, 24567SH00, 24568SH00, 25589SH00, 25590SH00, 25689SH00, 26742SH00
SIMILAC SENSIT PWD 12.0 OZ	70074057541	23390K800, 23424K800, 23428K800, 24454K800, 24483K800, 24486K800, 24488K800, 24506K800, 24517K800, 25591K800, 25592K800, 25678K800, 25678K801, 25735K800, 26741K800, 26743K800, 27879K800, 27948K800, 28021K800, 28144K800, 28145K800, 28146K800, 29191K800, 29192K800, 29234K800, 29236K800, 30300K800, 30339K800, 30446K800, 30450K800, 30451K800, 31471K800, 31472K800, 32619K800, 32620K800, 32628K800, 32629K800, 32630K800, 32682K800, 33705K800, 33711K800, 33712K800, 33714K800, 33831K800, 36091K800
SIMILAC SENSIT SPT-UP 12OZ	70074050960	25798K800
SIMILAC TOTL CMFRT PWD 12OZ	Not listed	24450K800, 24482K800, 24515K800, 24516K800, 24566K800, 25571K800, 25650K800, 25688K800, 26748K800, 26817K800, 26818K800, 26819K800, 26830K800, 26832K800, 26835K800, 27890K800, 28178K800, 28179K801, 28180K800, 29238K800, 31467K800, 31468K800, 31469K800, 32609K800, 32611K800, 33706K800, 33707K800

Manufacturer(s)

Abbott Nutrition Div Abbott Laboratories Inc, 2900 Easton Square Pl, Columbus, OH 43219, United States

Distributor(s)

McKesson Corp, 6555 State Hwy 161, Irving, TX 75039, United States

Summary

Update Reason: Distributor subrecall. This Alert provides information on a McKesson subrecall of the above powder infant formula based on a February 25, 2022, Urgent Drug Recall letter submitted by an ECRI member hospital regarding Alerts A38778 and A38778 01.

Problem

In a February 17, 2022, Press Release, Abbott initiated a recall of the above powder infant formula after four consumer complaints related to *Cronobacter sakazakii* or *Salmonella* Newport in infants who had consumed powder infant formula manufactured in the Sturgis, MI, facility. Abbott also states that as part of its quality process, it conducts routine testing for *Cronobacter sakazakii* and other pathogens in its manufacturing facilities; during testing in its Sturgis, MI, facility, the firm found evidence of *Cronobacter sakazakii* in the plant in non-product contact areas. Abbott further states that it found no evidence of *Salmonella* Newport; this investigation is ongoing. Abbott states that no distributed product has tested positive for the presence of either bacteria, and the firm continues to test. Abbott also states that it is recalling the powder formula manufactured in this facility with an expiration date of 2022 Apr 1. Products under recall have a multidigit number on the bottom of the container starting with the first two digits 22 through 37, and containing K8, SH, or Z2, with an expiration date of 2022 Apr 1. In a February 17, 2022, News Release, FDA warned consumers against use of affected powder infant formula.

Action Needed

Identify, isolate, and discontinue use of any affected powder infant formula in your inventory. If you have affected product verify that you have received the February 25, 2022, Urgent Drug Recall letter from McKesson. To schedule recalled product pick up, contact ABF by telephone at (866) 643-9477 or by e-mail at abbott@arcb.com. The carrier will provide a returns authorization (RA) number and a Bill of Lading. Print the recall signage that is attached to the letter. Post signage at the point of purchase at your retail establishment where any products in scope of the recall would normally be displayed for purchase. The signage must remain on display until FDA notifies Abbott that the recall is complete, upon which time Abbott will notify when the sign can be taken down. Do not remove signage until Abbott directs you to do so. Customers currently participating in a McKesson-administered Return to Vendor program should return the product to their designated returns processor. All others should follow the instructions provided by the manufacturer.

For Further Information:
McKesson
Website: Click here
Abbott
Website: Click here

Geographic Region(s)

(Impact in additional regions has not been identified or ruled out at the time of this posting), U.S.

Suggested Distribution

Infection Control, Nursery, Nursing, Obstetrics/Gynecology/Labor and Delivery, NICU, Pharmacy, Materials Management

Comment

- This alert is a living document and may be updated when ECRI receives additional information.

Miscellaneous

References:
Abbott. Press releases. Abbott voluntarily recalls powder formulas manufactured at one plant [online]. 2022 Feb 17 [cited 2022 Feb 18]. Available from Internet: Click here.
United States:

- Food and Drug Administration. News release—FDA warns consumers not to use certain powdered infant formula produced in Abbott Nutrition's facility in Sturgis, Michigan [online]. 2022 Feb 17 [cited 2022 Feb 22]. Available from Internet: Click here.
- Food and Drug Administration. FDA investigation of Cronobacter and Salmonella complaints: powdered infant formula (February 2022) [online]. 2022 Feb 20 [cited 2022 Feb 22]. Available from Internet: Click here.

Accession Number:	A38778 04	**ECRI Priority:**	High	**Published:**	05/12/2022
Channel:	Devices, Pharmaceutical, Food	**FDA:**	Not Specified	**Last Updated:**	05/12/2022

Concordance—Abbott Similac PM 60/40 Infant Powder Formula: Lots Manufactured at Sturgis, MI, Plant May Be Contaminated with Cronobacter sakazakii [Update]

Product Identifier(s)

Only product manufactured the Sturgis, MI, plant is affected. Lot number 27032K80 is for individual cans. Lot number 27032K800 is for cases.

Product	Abbott Nutrition Div Abbott Laboratories Inc Model	Concordance Healthcare Solutions Model	Product No.	Lot No.
Infant Powder Formula	Similac PM 60/40	521005	00850	27032K80, 27032K800

Manufacturer(s)

Abbott Nutrition Div Abbott Laboratories Inc, 2900 Easton Square Pl, Columbus, OH 43219, United States

Distributor(s)

Concordance Healthcare Solutions, 3901 W 34th St N, Sioux Falls, SD 57107, United States

Summary

Update Reason: Distributor subrecall. This Alert provides information on a Concordance subrecall of the above infant powder formula based on a February 28, 2022, Urgent Recall letter submitted by an ECRI member hospital regarding Alert A38778 02.

Problem

In a February 28, 2022, Urgent Voluntary Product Recall letter submitted by ECRI member hospitals, Abbott states that it is recalling the above lot of infant powder formula manufactured in Sturgis, MI. This is in addition to the lots of Similac, Alimentum, and EleCare powder formula that were recalled on February 17, 2022 (see Alerts A38778 and A38778 01). Abbott also states that this action comes after the firm learned of the death of an infant who tested who positive for *Cronobacter sakazakii* and who the firm was informed had consumed Similac PM 60/40 from the above lot. Abbott further states that this case is under investigation, and at this time the cause of the infant's *Cronobacter sakazakii* infection has not been determined. Abbott states that as part of its quality process, it conducts routine testing for *Cronobacter sakazakii* and other pathogens in its manufacturing facilities; during testing in its Sturgis, MI, facility, the firm found evidence of *Cronobacter sakazakii* in the plant in non-product contact areas. Abbott also states that no distributed product has tested positive for the presence of *Cronobacter sakazakii*. Abbott further states that recently tested retained product samples of the above lot were negative for *Cronobacter.* Abbott states that all infant formula powder finished products are tested for *Cronobacter* and other pathogens, and they must test negative before any product is released. The manufacturer has not confirmed the information provided in the source material.

Action Needed

Identify, isolate and discontinue use of any affected powder infant formula in your inventory. If you have affected product, verify that you have received the February 28, 2022, Urgent Recall letter and copy of the Abbott February 28, 2022, Urgent Voluntary Product Recall letter from Abbott. To arrange for product return, contact your Concordance customer service location by telephone using the information in the letter. Send a response to Concordance by e-mail at recallcoordinator@concordancehs.com to verify that you have received the letter.

For Further Information:
Concordance
Website: Click here
Abbott customer service department
Tel.: (800) 551-5838, 8:30 a.m. to 5 p.m. Eastern time, Monday through Friday
Abbott consumer relations department
Tel.: (800) 986-8540, 8:30 a.m. to 5 p.m. Eastern time, Monday through Friday
Website: Click here

Geographic Region(s)

(Impact in additional regions has not been identified or ruled out at the time of this posting), U.S.

Suggested Distribution

Infection Control, Nursery, Nursing, Obstetrics/Gynecology/Labor and Delivery, Home Care, NICU, Pharmacy, Materials Management

Comment

- This alert is a living document and may be updated when ECRI receives additional information.

Miscellaneous

References:
Abbott. Press releases. Abbott voluntarily recalls powder formulas manufactured at one plant [online]. 2022 Feb 17 [cited 2022 Feb 18]. Available from Internet: Click here.
United States:

- Food and Drug Administration. News release—FDA warns consumers not to use certain powdered infant formula produced in Abbott Nutrition's facility in Sturgis, Michigan [online]. 2022 Feb 17 [cited 2022 Feb 22]. Available from Internet: Click here.
- Food and Drug Administration. FDA investigation of Cronobacter and Salmonella complaints: powdered infant formula (February 2022) [online]. 2022 Feb 20 [cited 2022 Feb 22]. Available from Internet: Click here.